HFI-35 780

11/3/98

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
Fax (504) 589-4657

January 8, 1998

WARNING LETTER NO. 98-NOL-13

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Lichtenberger, CEO
Praxair, Inc.
P.O. Box 44
Tonawanda, New York 14150

Dear Mr. Lichtenberger:

During an inspection of your manufacturing facility, located at 56815 Evergreen Road, Plaquemine, Louisiana, conducted on December 4-11, 1997, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) regulations. These deviations cause your drug products, Oxygen USP and Nitrogen NF, to be adulterated within the meaning of Section 502(a)(2)(B), in that the controls used for the manufacture, processing, packing, or holding of these products are not in conformance with Current Good Manufacturing Practice regulations (Title 21, *Code of Federal Regulations*, Part 210 and 211).

Our inspection revealed the following CGMP deficiencies:

1. No documented evidence of the validation for the computer system or associated software that is responsible for the production, testing and release of Oxygen USP and Nitrogen NF;

2. Use of an unrecognized testing methodology for the testing and release of finished product Oxygen USP;

3. Use of an unrecognized testing methodology for the testing and release of finished product Nitrogen NF;

4. No review and approval by the Quality Control Unit of Oxygen USP and Nitrogen NF production and testing records prior to release for distribution.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

We recently received your firm's response to the FDA-483, issued on 12/11/97, as a result of the inspection. Your response, and attachments, have been forwarded to the Center for Drug Evaluation and Research, Rockville, Maryland for evaluation. We will provide a response to you after that evaluation has been completed by that office.

You should notify this office in writing, within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, you may contact Mr. Debo at telephone number (504) 589-7166.

Sincerely,

James E. Gamet
District Director
New Orleans District

cc: Mr. Gary L. Wilson, Facility Manager
Praxair, Inc.
P.O. Box 756
Plaquemine, Louisiana 70765

Enclosure: FDA-483

/tjt